Attachment 2

CQ HOMELAND SECURITY - WEAPONS
May 23, 2005 - 8:47 p.m.

Biodefense Industry Grumbling Over HHS Handling of Germwar Priorities

By Sean Madigan, CQ Staff

In the 10 months since Project BioShield was signed into law, the Department of Health and Human Services (HHS) has awarded three contracts worth about $1 billion for vaccines and countermeasures for the national stockpile.

Nearly all of that money will be spent on a vaccine for anthrax.

The government is also once again turning its eye to the threat of smallpox, issuing a new request for proposals (RFP) earlier this month for delivery of 20 million doses of a new smallpox vaccine.

To date, federal officials have focused almost entirely — and, biodefense experts say, rightly — on these two agents because terrorists could use them to inflict catastrophic attacks. But the government has identified at least two dozen other dangerous viruses and toxins as threats.

The biodefense industry knows the government wants new drugs and vaccines to beat the deadly agents. But it is not clear which countermeasure the feds will want next.

"It's pretty hard for people outside the government to figure out what the priority list is," Dr. J. Leighton Read, a venture capitalist at Alloy Ventures in California, told a Senate panel last month. "We have a long list of 20 or 30 agents, but the government's own thinking about rank and order of what comes after smallpox and anthrax for civilians in particular is obscure."

The list, Read said, should be "transparent, so the private sector can set priorities." Without that guidance, said John Clerici, an attorney at McKenna Long & Aldridge who advises a number of biodefense drug and vaccine makers, "it's a guessing game for industry to try and figure out what is next."

The intent of BioShield is to draw more companies into the biodefense market, which they have historically shunned because it is risky and unpredictable. BioShield creates markets for vaccines and countermeasures for which there is no commercial market. But the industry says the incentives do not go far enough, and that current laws still leave manufacturers vulnerable to product liability lawsuits.

So far, the program has done little to attract companies that are not already in the market.

Two new bills (S 3 and S 975) offering far more generous incentives were introduced earlier this year.

Along with anthrax and smallpox, the Centers for Disease Control and Prevention (CDC) lists botulism, plague, tularemia and viral hemorrhagic fevers such as Marburg and Ebola as Category A "select agents." These are the most dangerous agents, according to the CDC, because they can easily be disseminated or spread from person to person, have high mortality rates and could cause mass panic.

The government could use new countermeasures for each agent, but which one? When? And how many doses?

Knowing whether the government wanted 10,000 or 10 million doses of an Ebola countermeasure would help a company decide whether even to enter the market, Clerici said. "There has to be greater transparency. What is the list and what is the timetable?"

Murky Guidance

The guidance that industry has gotten on BioShield so far has been murky.

Executives and analysts used a May 2003 Congressional Budget Office (CBO) estimate for BioShield to speculate on how many doses of a new smallpox vaccine the government would want.

CBO estimated the government would buy 60 million doses of an experimental smallpox vaccine at $15 a dose — about a $900 million program over three years. But when HHS issued a draft RFP for the new vaccine on May 13, the document called for just 20 million doses, with an option to produce up to 60 million more.

The same CBO estimate anticipated the government would spend about $700 million on 60 million doses of anthrax vaccine during a three-year period.

Last November, HHS awarded a contract to a California company for 75 million doses of its experimental vaccine, a contract worth $877 million. HHS awarded a separate $123 million contract for 5 million doses of another anthrax vaccine. CBO also estimated HHS would spend $1.8 billion on botulinum toxin, $220 million on plague and $260 million on Ebola between 2004 and 2013.

Dr. Jerome Donlon, chief scientist at HHS' Office of Research and Development Coordination, said that figuring out what to buy, and when, is more complicated than just moving down the select agent list.

He said the decisions are based on material threat assessments conducted by the Department of Homeland Security. They factor in current intelligence data, the physical characteristics of the agents, plausible attack scenarios and the number of people who might be affected during the event.

"Its a deliberative process that everybody gets to opine in," Donlon said. He said anthrax, smallpox and botulinum are "clearly the top three" agents HHS has been concerned about.

HHS is also soliciting bids or industry feedback for an anthrax therapeutic, a botulinum countermeasure, an anti-radiation treatment and a nerve agent therapeutic. He said threat assessments are being conducted for agents such as tularemia and plague. He noted that the assessments, like the threats, are constantly changing.

Sean Madigan can be reached at smadigan@cq.com.

Source: **CQ Homeland Security**

Attachment 3

TOM DAVIS, VIRGINIA
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MINORITY MEMBER

ONE HUNDRED EIGHTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON GOVERNMENT REFORM
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Minority (202) 225–5051

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AND INTERNATIONAL RELATIONS
Christopher Shays, Connecticut
Chairman
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Washington, D.C. 20515
Tel: 202 225-2548
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February 18, 2005

The Honorable Donald H. Rumsfeld
Secretary of Defense
1000 Defense Pentagon
Room 3E880
Washington, DC 20301-1000

Dear Secretary Rumsfeld:

The Subcommittee on National Security, Emerging Threats, and International Relations, with oversight responsibilities for the Department of Defense (DOD), continues to pursue matters related to the health protection of armed forces.

Please provide to the Subcommittee current information on the status of the Joint Vaccine Acquisition Program (JVAP), types of vaccines involved, and a chart comparing the yearly accomplishments of the program from its beginning to date. Please also provide a detailed budget history of outlays by year and any studies, reports, or papers that have examined the JVAP program. Finally, please explain why DynPort Vaccine Co. was awarded a $19.7 million grant from the National Institute of Allergy and Infectious Diseases (NIAID) in December 2004 to develop the same vaccines included in the JVAP?

Please provide the information requested on or before the close of business March 18, 2005 to the Subcommittee office, room B-372 Rayburn House Office Building, Washington, D.C. 20515.

If you or your staff have any questions about this request, please contact Kristine McElroy, Professional Staff, at 202-225-2548.

Thank you for your attention to this request and for your assistance in the Subcommittee's oversight work.

Sincerely,

Christopher Shays
Chairman

UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000

PERSONNEL AND
READINESS

MAR 22 2005

The Honorable Christopher Shays
Chairman
Subcommittee on National Security, Emerging Threats
and Internal Relations
Committee on Government Reform
United States House of Representatives
Washington, DC 20515-0704

Dear Mr. Chairman:

This is in reply to your letter to Secretary Rumsfeld regarding the Joint Vaccine Acquisition Program (JVAP).

JVAP is part of the Joint Program Executive Office for Chemical and Biological Defense, which is the office responsible for advanced development of both medical products for the Department of Defense (DoD), including vaccines and therapeutics.

You also asked about a $19.7M grant awarded to DynPort Vaccine Company (DVC) in December 2004 by the National Institute of Allergy and Infectious Diseases (NIAID). The total amount is actually $29.2M over five years. This does not represent a single grant, but three separate grants and a contract to DVC for further development of medical countermeasures of mutual interest to both DoD and NIAID. These awards include two grants to support the development of a vaccine candidate for botulinum toxin, a grant to support a Phase II trial of a Venezuelan Equine Encephalitis vaccine, and a contract to fund research on a vaccine candidate for tularemia. In this manner, DVC's expertise in development of medical countermeasures for DoD can also be leveraged for civilian use.

Some of the medical countermeasures currently being developed through NIAID for the nation have their technology basis in programs which originated in DoD. As such, DoD and NIAID work cooperatively together to leverage medical countermeasure programs of mutual interest including the role played by the DVC for such development. Both DoD and NIAID have reviewed their programs to ensure there is no funding redundancy.

Thank you for your current interest in the DoD role to develop medical countermeasure to protect our Service members and your desire to work cooperatively with other government agencies to benefit the nation.

Sincerely,

Michael W. Wynne
Acting

Enclosure:
As stated

cc:
The Honorable Dennis J. Kucinich
Ranking Member

Attachment 4

washingtonpost.com

. . . We're Unprepared

America is still vulnerable to a biological attack.

By David Ignatius
Post
Friday, May 20, 2005; A21

Suppose the single-engine Cessna that flew through restricted airspace toward the White House on May 11 had been piloted by a terrorist, rather than a retired farmer. And suppose the plane had been carrying a deadly payload of anthrax spores or some other biological weapon. That was one of the terrifying possibilities that triggered the rushed evacuation of the Capitol, the White House and other buildings that day.

Now suppose we are conducting a postmortem investigation of how well the nation was prepared for such a biological attack. Think of the exercise as a "May 11 Commission," a mini-version of the exhaustive report that was prepared after the Sept. 11, 2001, attacks. The likely conclusion of our imaginary panel can be summed up in one sentence: America is shockingly unprepared for bioterrorism.

There's no way to know how many people would be affected by such an attack. One simulation done by a major defense contractor estimated that an airborne bioterrorist assault on Washington would bring tens of thousands of potential casualties within the first 10 minutes and hundreds of thousands within the first five hours.

Certainly, as with Sept. 11, the warning signs are flashing red. The recent report by the commission on weapons of mass destruction noted that al Qaeda conducted "extensive, well-organized" research and planning for a biological attack, starting in 1999. Past studies have described anthrax laboratories in Afghanistan, but the commission report mentions an especially deadly toxin it describes only as "Agent X." The report notes that the terrorist group " 'probably' acquired at least a small quantity of this virulent strain and had plans to assemble devices to disperse the agent." How much more warning do we need?

For help in my imaginary postmortem, I turned to a leading expert in the field, Tara O'Toole, who is director of the Center for Biosecurity sponsored by the University of Pittsburgh Medical Center. She says a key problem in the event of an attack would be the lack of preparedness at hospitals. They need better systems for triage after a biological attack, better protection for health care workers and, most important, the ability to immunize large numbers of people quickly. What's more, there's no rapid clinical diagnostic test available today for anthrax, according to O'Toole, even though one could be produced with current technology.

The most surprising vulnerability to biological attack is the lack of electronic connectivity among hospitals. O'Toole estimates that only 10 percent of the country's hospitals have electronic record systems that allow rapid sharing of medical information. Without them, epidemiologists would have trouble seeing patterns of exposure to an attack -- or even being certain that it had occurred. For the first

24 hours, physicians might simply be guessing. "Medical surveillance is the single most important component of a biodetection architecture," noted a 2003 study by a scientific panel known as JASON. But this is now a weak link.

The Washington area is believed to have an extensive network of sensors that, in theory, should warn of a biological attack. But it's not clear that these sensors would actually pick up the presence of anthrax or other toxins. And since it often takes 24 hours to collect and analyze the specimens, the sensors might not pick up a stealth attack any more quickly than would doctors, diagnosing the symptoms of individual patients.

O'Toole fears that much of the roughly $27 billion the federal government has spent on civilian biodefense since 2001 has produced only modest results. The main achievement, she says, has been development of a stockpile of smallpox vaccine. Billions of dollars have been doled out to state governments for public health preparedness, but this money has often gone to supplant other health care spending.

Nearly four years after Sept. 11 and the anthrax mail attacks, the United States still lacks a coherent overall strategy for dealing with bioterrorism. The Department of Homeland Security is supposed to be developing a threat assessment, which in turn would drive planning by the Department of Health and Human Services. But O'Toole says this strategic plan hasn't yet been completed. Without it, there can be little progress on the drug countermeasures that, in theory, would be funded through the Bioshield program that became law last year.

The Cessna that approached the capital on May 11 was flown by a couple of off-track amateur pilots. But it's useful to imagine a real attack -- and to realize how ill-prepared the country is. Nearly four years after what should have been the wake-up call, says O'Toole, "We're not much better off than we were. There's no strategy for setting national priorities, and no one in charge of creating a robust biodefense."

We can see this one coming at us, as clear as that little single-engine plane. It's intolerable that the nation isn't better prepared.

davidignatius@washpost.com

Attachment 5

FISCAL 2006 APPROPRIATIONS:HOMELAND SECURITY - STEWART SIMONSON
2,231 words
28 April 2005
Congressional Testimony by Federal Document Clearing House
English

Statement of Stewart **Simonson**, J.D. Assistant Secretary, Office of Public Health Emergency Preparedness U.S. Department of Health and Human Services

Committee on Senate Appropriations Subcommittee on Homeland Security

April 28, 2005

Good morning, Mr. Chairman, Senator Byrd and Subcommittee members. I am Stewart **Simonson**, Assistant Secretary for Public Health Emergency Preparedness. I appreciate the opportunity to share with you information on our progress in implementing the Project BioShield Act of 2004, which was enacted some nine months ago. Biodefense is a top priority for the Bush Administration and having an appropriate armamentarium of medical countermeasures is a critical aspect of the response and recovery component of the President`s ``21st Century Strategy for Biodefense.`` The acquisition and ready availability of medical countermeasures, such as antibiotics, monoclonal and polyclonal antibodies against infectious threats, therapies for chemical and radiation-induced diseases, and vaccines to protect against exposure from biological agents will have a substantial impact on our preparedness and response capabilities.

Protecting Americans

The events of September and October 2001 made it very clear that terrorism indeed bioterrorism is a serious threat to our Nation and the world. The Bush Administration and Congress responded forcefully to this threat by seeking to strengthen our medical and public health capacities to protect our citizens from future attacks. The Bioterrorism Act of 2002 substantially increased funding authorization for the Centers for Disease Control and Prevention`s **Strategic** National Stockpile. To encourage the development of new medical countermeasures against biological, chemical, or radiological agents and to speed their delivery and use in the time of an attack, President Bush, in his 2003 State of the Union address proposed and Congress subsequently enacted the Project BioShield Act of 2004. The Special Reserve Fund, pre- appropriated with $5.6 billion was created to assure developers of medical countermeasures that funds would be available to purchase critical products for use to protect our citizens.

The **Strategic** National Stockpile Today

The wake-up call that we received in the fall of 2001 brought clarity to the gaps in our chemical countermeasure armamentarium and we immediately sought to address them. Although there is much work still to be done, we have made significant progress in building our **Strategic** National Stockpile from that time to what we have on-hand today. For example, our smallpox vaccine stockpile has grown from 90,000 ready-to-use doses in 2001 to enough vaccine to protect every man, woman, and child in America. Major strides have been made in building our chemical countermeasure reserve against anthrax, plague, and tularemia. We are now able to protect and treat millions of Americans in the event of an attack with one of these agents. We have taken the botulism antitoxin program started by the Department of Defense in the early 1990s to completion and we are now building our antitoxin stockpile further. We have also built our stockpile of countermeasures to address the effects of radiation exposure with products such as Prussian Blue and diethylenetriaminepentaacetate, or DTPA. These countermeasures act to block uptake or remove radioactive elements such as cesium, thallium, or americium from the body after they are ingested or inhaled. Potassium iodide, a drug that can protect the thyroid from the harmful effects of radioactive iodine, is also in the Stockpile.

The **Strategic** Approach to Addressing Medical Countermeasure Gaps

The initial focus of our efforts to protect the nation was aimed largely at those threats that could do the greatest harm to the

greatest number of our citizens, namely, smallpox and anthrax. A sense of urgency has pervaded our efforts and has defined new ways of doing business. Our new national security environment demanded accelerated product development timelines and new paradigms of interactions between industry and government with risk-sharing and enhanced intra-governmental collaboration. Using a robust interagency process, that mined intra- and extra- governmental expertise, requirements for medical countermeasures were identified, and options elaborated for addressing immediate and long-term needs. These experts continue to help us define the most expeditious way to traverse the critical pathway to develop and acquire usable countermeasures for the **Strategic** National Stockpile.

Application of the **strategic** approach: Anthrax.

Although not transmissible from person-to-person, an attack involving the aerosol dissemination of anthrax spores, particularly in an urban setting, was considered by public health experts to have the potential for catastrophic effects similar to smallpox... The potential for large-scale population exposure following aerosol release of anthrax spores, the threat demonstrated by the anthrax letters, and our knowledge that anthrax had been weaponized by state-actors, highlighted the nature of the treat. The Secretary of the Department of Homeland Security determined that anthrax posed a material threat to the Nation. And, because untreated inhalation anthrax is usually fatal, the Secretary of HHS identified anthrax as a significant threat to public health.

The approach to protect citizens against this threat demanded immediate, intermediate and long-term strategies and requirements. First, the existing stockpile of antibiotics in the **Strategic** National Stockpile was increased. Second, there was a need for a licensed vaccine to be used not only for pre-exposure protection for laboratory and other workers at known risk for anthrax, but for use along with antibiotics after an exposure to potentially decrease the currently recommended 60-day course of antibiotic therapy. Anthrax spores are stable in the environment and would have a profound impact if released in an urban population. Availability of a vaccine is a critical requirement for repopulation and restoration of the functionality of any exposed area.

The limitations inherent in the currently available anthrax vaccine were articulated in a 2002 Institute of Medicine report, ``Anthrax Vaccine: Is It Safe? Does it Work?`` The report stated, ``...a new vaccine, developed according to more modern principles of vaccinology, is urgently needed.`` An assessment of developing technologies was undertaken by HHS experts in the fall of 2001 and the decision was made that there was a sufficient scientific foundation, including a detailed understanding of the pathogenesis of anthrax and how anthrax vaccines provide protective immunity, to support the aggressive development of a next generation vaccine consisting of recombinant protective antigen (rPA). This research, spanning more than a decade from its inception in the early 1990s, was conducted in large part by the United States Army Medical Research Institute of Infectious Diseases at Fort Detrick, Maryland.

HHS defined a three-stage development and acquisition strategy with open competition for awards at each stage. The early and advanced development programs were supported by the National Institutes of Health`s National Institute of Allergy and Infectious Diseases with contract awards in September 2002 and 2003, respectively. These were milestone-driven contracts with well-defined deliverables including the manufacture of clinical- grade vaccine and the conduct of Phase 1 and Phase 2 clinical trials. Large-scale manufacturing capacity would be required to support the civilian requirement for this medical countermeasure, which was defined through an interagency process to be the initial protection of up to 25 million persons. Senior officials throughout the United States government evaluated acquisition options to achieve this requirement and, in the fall of 2003, the decision was made to pursue the acquisition of rPA anthrax vaccine.

An evaluation of the status of the NIAID rPA anthrax vaccine development program suggested rPA vaccine could potentially become a licensed product within 8 years. In March 2004, the acquisition program for this vaccine, under the direction of my office, was launched using the Special Reserve Fund created in the FY 2004 Department of Homeland Security appropriations bill. Utilizing a robust technical and business evaluation process, we reviewed multiple proposals and finally negotiated a contract with VaxGen of Brisbane, California, for 75 million doses of the vaccine, (anticipating a three-dose regimen). Using a milestone and deliverables approach utilized with the ACAM2000 smallpox vaccine development and acquisition program, and the rPA anthrax vaccine development related contracts at NIAID, the VaxGen contract lays out an ambitious program to include the delivery of the first 25 million usable vaccine doses to the **Strategic** National Stockpile within 2 years of contract award. A unique and critical aspect of the rPA vaccine BioShield acquisition contract is the fact that no payment is made until a usable product is delivered to the Stockpile. While awaiting delivery of this new vaccine to the Stockpile my office will complete negotiations for 5 million doses of the currently licensed anthrax vaccine in the next few days to support immediate requirements. Delivery of the product to the Stockpile will begin very soon after the contract award and will have a direct impact on our preparedness.

Other Needed Countermeasures.

In an effort to fill other gaps in the Stockpile, we have made progress in contracting for products that will soon be delivered for use.

Potassium Iodide.

In March 2005 a contract was awarded under Project BioShield for a pediatric liquid formulation of potassium iodide, a drug that helps limit risk of damage to the thyroid, from radioactive iodine. This formulation is aimed at young children who cannot take pills and are at the highest risk of harmful effects from exposure to radioactive iodine. This acquisition will provide needed protection for at least 1.7 million children. Product delivery will begin next month.

Ongoing Project BioShield activities.

In addition to the Project BioShield acquisition contracts that have been awarded in the last nine months, there are several other important BioShield procurement-related activities underway. We are reviewing the responses for Requests for Proposals for anthrax therapies, and we are continuing to move forward on the acquisition of an antitoxin treatment for botulism. Furthermore, to signal our intent to acquire a next generation smallpox vaccine, we will be releasing a draft request for proposal for industry comment within the next two weeks. Finally, in anticipation of yet to be determined requirements, we actively monitor the state of the medical countermeasure pipeline- - both within and outside the government--- by evaluating USG research and development portfolios and engaging industry through the publication of Requests for Information (RFIs). For example, we have recently released three RFIs to assess the timeline to maturity of medical countermeasures to treat nerve agent exposure, acute radiation syndrome, and additional products that might be available to treat anthrax. These requests are a key tool for HHS to dialogue with industry partners and to inform the development of sound USG acquisition strategies.

Priority Setting Beyond Smallpox and Anthrax

The approach taken to rapidly expand our Nation`s response capacity to meet the medical and public health impact of either a smallpox or anthrax attack demonstrate our national resolve to address these threats. But, in many ways, anthrax and smallpox represent the ``low hanging fruit`` for medical countermeasure research, development and acquisition and was enabled by a substantial research base developed by USAMRIID and NIH. There was consensus that these were our highest priorities and we had countermeasures available or relatively far along in the development pipeline to permit acquisition. Given an almost endless list of potential threats with finite resources to address them, prioritization is essential to focus our efforts. We rely heavily upon our interagency partner, the Department of Homeland Security, to provide us with a prioritized list of threats along with material threat assessments that will provide reasonable estimates of population exposure. This information is critical for future **strategic** decision making regarding how best to focus our National efforts in countermeasure development and acquisition, including whether in the short-term, the so-called ``one-bug, one-drug`` approach should continue while simultaneously investing in more broad-spectrum prevention and treatment approaches for the longer term.

Challenges to Rapidly Expanding the **Strategic** National Stockpile

Although defining priorities and quantifying the size of the threat to the population are the key steps to focus our efforts, we must be mindful of the realities of the spectrum of efforts needed along the research and development pipeline to produce a useable medical countermeasure. The process of defining required specifications for a countermeasure often reveals few, if any, candidates in the pipeline. Basic research and early development efforts, even when robustly funded, often take years before a concept is mature enough for advanced development. When a product has reached the advanced development stage, Project BioShield Act of 2004 provides an important incentive for manufacturers to take the product the rest of the way through the pipeline. And, as I have outlined here today, in the 9 months since Project BioShield was enacted, the incentive has sped final development of several products for the Stockpile.

Conclusion

In closing, I must emphasize that the number of threat agents against which we could guard ourselves is endless and new and emerging threats introduced by nature will present continuing challenges. Although we cannot be prepared for every threat, we have the ability to create a **strategic** approach to identifying and combating the greatest threats. HHS and its agencies including NIH, CDC, and FDA, have a clear mandate from President Bush and Congress to lead the charge in this arena. We have already made important strides and will continue to work to address the obstacles identified. Mr. Chairman, I look forward to working with you and members of the Subcommittee to address the challenges of bioterrorism preparedness and its impact on public health.

I will be happy to answer any questions you may have.

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